

REMARKS/ARGUMENTS**35 U.S.C. § 112 first paragraph**

Claims 11-16, 32, 33 and 39-46 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. Applicants traverse this rejection.

Applicants maintain that claims to a pharmaceutical composition and a method of treating a human who is infected with hepatitis C virus are enabled. Immunizing mice with a DNA vaccine against HCV and measuring an immune response is an accepted model for DNA vaccination against HCV to raise a therapeutic immune response in a human subject. The experimental evidence in the specification correlates an *in vitro* or *in vivo* animal model assay to a disclosed or claimed pharmaceutical composition or a method of inducing an immune response against hepatitis C virus in a human.

Applicants have cancelled claims 11-16, 32, 33 and 39-46 solely to facilitate prosecution of the application and without prejudice to pursuing these claims in a continuing application.

35 U.S.C. § 102(e)

Claims 3, 4, 6, 8, 11-13, 34, 36, 38, 39-41 and 45-46 were rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Maertens et al. (U.S. 6,180,768 B1). Applicants traverse the examiner's rejection.

The rejection of claims 3, 4, 6, 8, 11-13, 34, 36, 38, 39-41 and 45-46 under 35 U.S.C. § 102(e) in view of Maertens et al. is obviated because U.S. patent 6,180,768 has been withdrawn from grant by the U.S. Patent and Trademark Office on February 17, 2001.

A person shall be entitled to a patent unless "the invention was described in (1) an application for patent published under 122(b), by another filed in the United States before the invention by the applicant for patent, or (2) a patent granted on an

application for patent by another filed in the U.S. before the invention by the applicant for patent."

35 U.S.C. § 102(e). Regarding U.S. patent 6,180,768, no application has been published in the United States and the U.S. patent has been withdrawn from grant by the U.S. Patent and Trademark Office and has not been published. A rejection under 35 U.S.C. § 102(e) in view of U.S. patent 6,180,768 cannot be maintained and is moot.

Therefore, the rejection of claims 3, 4, 6, 8, 11-13, 34, 36, 38, 39-41 and 45-46 under 35 U.S.C. § 102(e) in view of U.S. patent 6,180,768 is moot.

35 U.S.C. § 103(a)

Claims 3, 4, 6-8, 11-28, and 34-46 were rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over Maertens et al. (U.S. 6,180,768 B1) or Selby et al. (*J. Gen. Virol.*, **74**: 1103-1113, 1993) in view of Tokushige et al. (*Hepatology* **24**: 14-20, 1996) and Ferrari et al. (*Hepatology* **19**: 286-295). Applicants traverse the rejection.

For the reasons stated above the rejection of claims 3, 4, 6-8, 11-28, and 34-46 under 35 U.S.C. § 103(a) over Maertens et al. (U.S. 6,180,768 B1) in view of the Tokushige et al. reference and the Ferrari et al. reference is moot since U.S. patent 6,180,768 was withdrawn from grant by the U.S. Patent and Trademark Office.

Claims 3, 4, 6-8, 11-28, and 34-46 are not obvious over the Selby et al. reference in view of the Tokushige et al. and the Ferrari et al. references. The examiner has not established a *prima facie* case. To establish a *prima facie* case of obviousness, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The examiner has failed to establish a *prima facie* case because the Selby et al. reference in view of the Tokushige et al. reference and the Ferrari et al. reference do not teach or suggest a recombinant nucleic acid molecule comprising a hepatitis

C non-structural protein, operably linked to a promoter, enhancer, polyadenylation sequence, and a 5' UTR of hepatitis C virus. Furthermore, the combination of references do not teach or suggest a method of inducing an immune response against hepatitis C virus in a human comprising administering a nucleotide sequence encoding a hepatitis C virus nonstructural protein.

The examiner furthermore provides no motivation to combine the various results in the cited references to obtain applicants' claimed invention. The examiner provides no motivation to combine the full-length coding region of the hepatitis C virus expressed in mammalian cells by transfection in the Selby et al. reference with the plasmid constructs expressing HCV core protein generate a strong CTL response in the Tokushige et al. reference and with the T cell proliferative responses to hepatitis C virus core protein and NS protein in HCV antibody positive human subjects in the Ferrari et al. reference. The examiner does not obtain applicants' claimed invention. The examiner provides no motivation to combine the vector constructs expressing the HCV core protein of the Tokushige et al. reference with the vector constructs expressing the full length coding region of the hepatitis C viral genome or subgenome of the Selby et al. reference, with the T-cell response to structural and nonstructural hepatitis C virus antigens, and thereby the examiner does not obtain applicants' claimed invention.

Accordingly, applicants respectfully request that the rejection of claims 3, 4, 6-8, 11-28, and 34-46 under 35 U.S.C. § 103(a) be withdrawn.

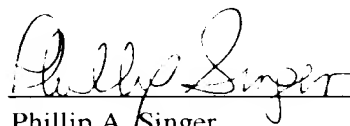
CONCLUSION

In view of the foregoing, applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-332-1380.

Respectfully submitted,

Date: June 30, 2003



Phillip A. Singer
Registration No. 40,176

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439